# Exhibit 56

**CONFIDENTIAL**

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**INTEROFFICE MEMORANDUM**

DATE: January 30, 2000

TO: R. Meli; R.S. Bernstein; E. Turner

FROM: R. J. Zazenski

**SUBJECT: ACTION PLAN *RECOMMENDATIONS* for FINAL PHASE of NTP TALC REVIEW PROCESS**

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**Executive Summary**

The National Toxicologicol Program's (NTP) carcinogenic review of talc has entered the final phase of a four-step review process that will conclude with a listing recommendation by the NTP Executive Committee sometime later this year. The threat of an NTP listing nomination for non-asbestiform talc remains a distinct and real possibility.

The following actions have been identified as practical strategies that can be implemented by Luzenac America to help preclude an NTP listing recommendation:

- Continue to emphasize the critical nature of the talc definition debate and how it has undermined the validity of the NTP reviews and recommendations.
- Highlight the "superior reasoning" employed by the RoC Subcommittee (December meeting) and provide supportive documentation to agencies represented on the NTP Executive Committee.
- Utilize Freedom of Information Act (FOIA) requests to examine internal documents from NTP and FDA relating to prominent issues cited in the NTP talc review process.
- Lobby support from elected state and federal government officials.
- Continue to assist and support CTFA coordinated initiatives.
- Maintain on-going dialogue and counsel with the Center for Regulatory Effectiveness.

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**Current Status**

Talc (asbestiform and non-asbestiform) has been reviewed by three of four NTP technical committees. The next step will be a solicitation of public comments on the recommendations of the three completed reviews. All recommendations and public comments will then be presented to the NTP Executive Committee for review and recommendations. All the recommendations will then be presented to the Director of NTP for a final recommendation to the Secretary, Health and Human Services.

The Federal Register official notice soliciting public comment is expected in early February. The meeting of the Executive Committee is not expected to take place until September or October of 2001.

**Significant Issues**

- Non-asbestiform talc was recommended for NTP listing by the first two review groups (RG1 & 2) by votes of 6-1 and 7-1. This overwhelming margin of 13-2 suggests that the reviewers found the epidemiology studies associating talc and ovarian cancer provided convincing evidence of talc carcinogenicity in humans.

- The primary reason non-asbestiform talc was able to survive the third NTP meeting in December and not be recommended for listing was the introduction of doubt concerning the characterization of talc utilized in dusting powders cited in the epidemiology studies. All but one of the sixteen ovarian cancer

studies would have involved the use of cosmetic talc and baby powder produced prior to 1976, the year that CTFA introduced cosmetic talc specifications requiring no asbestos. This point received considerable discussion at the third meeting. However, as debate wore on, it became apparent that some reviewers were beginning to suggest that this asbestos contamination issue should be considered as an additional "confounding factor" in the studies, thereby allowing the study results to be validated and applied to non-asbestiform talc. This "data accounting adjustment" would lower the value of the epidemiology results to a *limited evidence* category (as opposed to *sufficient evidence*), but it would still allow it to qualify as a valid human study for NTP listing purposes.

- Despite the solid technical presentations and submittals by the medical experts hired by the CTFA for the December NTP meeting, it was apparent that the NTP reviewers were only marginally influenced by their arguments. The "bottom-line" for these reviewers was that *fourteen of sixteen* epidemiology studies showed a statistical association between talc and ovarian cancer. The *quantity* of the evidence seemed to trump arguments over the *quality* of the evidence. This same view of the *quantity* of human evidence (versus the quality) will likely be *even more* of an influencing factor at the "non-technical" NTP Executive Committee review.

- The review of the carcinogencity of asbestiform talc is so mired in confusion at this point because of the definition debate, there is no way of predicting how this issue is going to be presented to the Executive Committee. The first two review groups viewed this category as talc containing asbestos fibers, while the third review group redefined it as "talc containing asbestiform minerals, not asbestos". This definition does not even fit any of the talc categories discussed in the NTP Draft Document.

- Despite the victory for non-asbestiform talc in December, NTP can still re-package the data and salvage a formidable argument against non-asbestiform talc for presentation to the Executive Committee. The epidemiology studies can be presented to show *limited human evidence* in 14 out of 16 studies; and the NTP animal studies can be presented to show *limited animal evidence* in female rats at a talc exposure level of only 9x the current TLV for talc (2 mg/m3 – workday exposure). Given that there is little or no preparation by the Executive Committee members prior to the meeting, little substantive debate is said to take place (meeting are closed – limited 'intelligence' obtained from CRE). The committee usually votes the recommendation favored by the NTP presenter.

- The threat of litigation against NTP may be the primary (and perhaps the only) real weapon we have in our arsenal that might discourage them from listing talc. While I believe the NTP can readily achieve a listing recommendation at the Executive Committee level, NTP cannot erase from the public record the embarrassing debacle that occurred in December. Hopefully, if NTP suspects that their entire talc nomination review could be in jeopardy because of this definition issue, they may want to avoid a public battle that could prove embarrassing – and therefore not recommend listing at the Executive committee meeting. If they do not feel threatened by potential court action, then litigation on this talc issue becomes a real possibility.

**Recommended Strategy – Action Items**

At this "eleventh-hour" stage of the talc review process, our opportunities for influencing the outcome are limited. Given this narrow window of opportunity, the following actions are recommended:

- **"Confusion" over Talc Definition Issue** – We need to continue to "hammer-away" at NTP leadership on this issue. A formal request will be submitted to NTP insisting that the recommendations of RG 1 & 2 be withdrawn from consideration in light of the debate that occurred at the December meeting. This request will be tendered by CRE *directly* to the NTP Director and Secretary while similar written requests to the Executive Committee can be submitted by Luzenac America, Eurotalc, CTFA, and any other talc-interested-party we can recruit for added emphasis. CRE has already provided Luzenac with a draft letter for our critique. Luzenac will bring this issue forth at a special meeting of the CTFA on February 19.

  **Timing** – CRE letter mailed by Feb. 1. Luzenac letter – Feb/Mar

• **Highlighting the Rationale for RoC Subcommittee Vote** – Assuming that NTP will not withdraw the recommendations of RG1 & 2, we need to bring to the forefront the "superior reasoning" employed by the RoC Subcommittee at the December meeting and why the Executive Committee should sustain a no-listing recommendation for talc (non-asbestiform). This submission can take place during the formal public comment period. The first step in implementing this strategy will be to scrutinize the transcript from the December meeting and extract supporting quotes and comments. We will then highlight specific issues and distribute them among targeted agencies represented on the Executive Committee. In conjunction with this action, we need to identify potential agency allies and find a way to ensure that they stand up for "their" position (pro-talc) in the Executive Committee meeting.

**Timing** – Within 60 days of release of transcript (Mar/Apr)

• **Freedom of Information Act Requests (FOIA)** - To attempt to learn who voted against the listing proposal in RG1 and RG2 (potential allies), CRE will file FOIA requests with both NTP and FDA. The FOIA requests will also focus around the 1994 FDA talc workshop to determine if additional internal FDA views can be uncovered concerning the 1993 NTP animal study. It is also possible that materials uncovered from NTP would assist Luzenac in potential litigation by documenting misrepresentations of data or omissions of key data in the RG1 & RG2 reviews.

**Timing** – FOIA requests mailed week of Jan. 30

• **Support from Elected Representatives** - U.S. Senators and Congressmen from Montana and Vermont will be lobbied to lend support to this issue. The Rio Tinto Washington office will also be asked to identify other government officials who could be called upon to lend assistance.

**Timing** – Requests will be submitted 60 day prior to Executive Committee meeting.

• **Continued Support of CTFA Initiatives** – The CTFA will continue to challenge the listing recommendations of RG 1 & 2 by enlisting the support of prominent medical experts. The CTFA talc task force committee will meet February 19 to delineate an action plan for this final NTP review phase.

**Timing** – Strategy meeting Feb. 19

• **Maintain on-going Counsel with the Center for Regulatory Effectiveness** - Luzenac will continue to solicit the input and advice from CRE as it relates to (1) actions CRE can instigate to continue "watchdog" pressure on NTP; (2) actions and strategies Luzenac and other "talc-interested-parties" should employ in advance of the meeting of the NTP Executive Committee; (3) fundamental actions Luzenac needs to undertake to reinforce our legal foundation in the event litigation is required.

**Timing** – Ongoing

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